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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,055	10/22/2003	Craig D. Friedman	298801-00021 (227856)	7247

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EXAMINER	
HEYER, DENNIS	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
09/24/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipmail@eckertseamans.com

Office Action Summary	Application No.	Applicant(s)	
	10/692,055	FRIEDMAN ET AL.	
	Examiner	Art Unit	
	DENNIS HEYER	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 3, 5, 7, 9 – 12, 61, 63 – 68, 72 – 76, 79 – 98 and 100 – 111* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 2, 3, 5, 7, 9 - 12, 61, 63 - 68, 72 - 76, 79 - 98 and 100 - 111 .

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment/Remarks filed February 18, 2009. Claims 69 and 99 are cancelled. Claim 111 is new. Claims 2, 10, 84 and 89 are currently amended. The limitations from cancelled Claims 69 and 99 have been incorporated into independent Claims 2 and 84. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 2, 3, 5, 7, 9 – 12, 61, 63 – 68, 72 – 76, 79 – 98 and 100 – 111 are currently pending.

Withdrawn Objections and/or Rejections

Withdrawn Objections

The objection to Claims 10 and 89 are withdrawn in light of Applicant's amendments.

Withdrawn Rejections

Claim Rejections - 35 USC § 112 2nd Paragraph

The rejection of Claims 2, 3, 5, 7, 9 – 12, 61, 63 – 69, 72 – 76, 79 – 110 under 35 U.S.C. 112 2nd paragraph, as being indefinite regarding the term 'resilient' is withdrawn in response to Applicant's arguments. It is noted that in the absence of any quantitative or measure of 'resiliency' this limitation will be given a broad interpretation.

The rejection of Claims 2, 84 and 109 under 35 U.S.C. 112 2nd paragraph, as being indefinite regarding the term 'at least partially hydrophobic' is withdrawn in response to Applicant's arguments. It is noted that in the absence of any quantitative or measure of 'partial hydrophobicity' this limitation will also be given a broad interpretation.

Claim Rejections - 35 USC § 102

The rejection of Claims 84, 86 – 97 and 100 – 108 under 35 U.S.C. 102(a/e), as being anticipated by Thomson (US 2002/0018884 A1), is withdrawn in response to Applicant's amendment to Claim 84.

Claim Rejections - 35 USC § 103

The rejection of Claims 85, 98, 99, 109 and 110 under 35 U.S.C. 103(a) as being unpatentable over Thomson (US 2002/0018884 A1) in view of Pinchuk (USPN 5,229,431) is withdrawn in response to Applicant's amendment to Claim 2.

The rejection of Claims 2, 5, 7, 9 – 12, 61, 63 – 67, 72 – 74, 76, 79 – 83 under 35 U.S.C. 103(a) as being unpatentable over Thomson (US 2002/0018884 A1) in view of

Van Antwerp (US 2003/0031699 A1) is withdrawn in response to Applicant's amendment to Claim 2.

The rejection of Claims 3, 68 and 69 under 35 U.S.C. 103(a) as being unpatentable over Thomson (US 2002/0018884 A1) in view of Van Antwerp (US 2003/0031699 A1) and further in view of Pinchuk (USPN 5,229,431) is withdrawn in response to Applicant's amendment to Claim 2.

Response to Arguments

As noted above, the rejections and objections applied in the Office action filed August 18, 2008 are withdrawn in response to the Applicant's amendments dated February 18, 2009. Applicant argues that it is inappropriate to combine the Thomson and Pinchuk references as they are drawn from different types of polymer technology and that such a "mix and match" approach to combining features is contrary to law and contrary to common sense (response, page 12). The Examiner respectfully disagrees. It is the position of the Examiner that features of different 'technologies' may be properly combined if they are directed toward, in this case, resolving a common problem in the medical device art (i.e. would provide an expected advantage). In this specific case it is not the resistance to cracking, although that is indeed a desirable property of a biomaterial, but the teaching by Pinchuk that a polyurethane – polycarbonate copolymer is an attractive alternative to the polyether urethanes of Thomson in that they are more resistant to enzymatic biodegradation (presumably at the ether linkage site; see

Pinchuk, column 6, lines 45 – 68 and column 7, lines 1 – 12). Thus, combining the features of Thomson, a reticulated, elastomeric, foam polyurethane matrix with the polyurethane-polycarbonate of Pinchuk would be quite sensible, especially in light of the numerous bio-relevant embodiments taught by Thomson in which the polyurethane foam matrix serves as a femoral shunt, a drug delivery device, or a device to remove drugs from blood (Thomson, Figures 18, 20 and 22). Further, there is ample legal precedent to combine a features from references if the prior art suggests an expected benefit would result from their combination (see MPEP 2144 [R-6] section II, which discusses expectation of advantages as a strong rationale from combining references).

Applicant further argues that Thomson does not teach an 'implant' and, accordingly, does not meet each and every limitation of the Claims. Strictly, this is true, Thomson does not disclose an implant per se, although it is clear that from the disclosure of Thomson that polyurethane foams are clearly biocompatible materials and thus are implantable. The intended use as cited in the preamble of a Claim is not relevant as the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use (implantation into a patient's body), then it meets the claim (MPEP 2111.02, II).

Applicant argues that Thomson does not disclose a hydrophilic coating comprising a biodegradeable polymer (response, page 11). In response the Examiner

cites the Office Action of August 18, 2008 (page 6) in which Thomson discloses hydrogel coatings based on polysaccharides, which may be biodegradeable.

Applicant argues that the 103(a) rejection citing a combination of Van Antwerp and Thomson is inappropriate as the non-reticulated chemistry of Van Antwerp is different from that of Thomson (page 13, response). It is the position of the Examiner that the incorporation of a known drug release architecture (microsphere encapsulation into a hydrophilic polymeric coating) in order to gain the art-recognized benefit of said architecture (further modulating or controlling release of the drug or active agent) is indeed a strong motivation to combine the teachings of Thomson and Van Antwerp as there is a reasonable expectation of success (absent a showing of specific evidence to the contrary of an unexpected result).

Finally, Applicant notes that, presumably in reference to the interview of record on April 17, 2008 that the Examiner's indicated that Claim 75 contained allowable subject matter and argues that it is unclear why Claim 84, allegedly Claim 75 written in independent form, is currently rejected over Thomson. In response the Examiner notes that the summary of said interview notes that an additional search would be required to determine if the Claims were indeed free of the prior art. The rejection of the limitation in Claim 75 requiring a biodegradeable polymer is cited below as being disclosed by Thomson.

New Rejections

Claim rejections – 35 USC § 112 – 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 111 recites the limitation "at least 5 – 50 % by weight of 2, 4'-MDI" in the polycarbonate polyurethane scaffold. This Claim is indefinite as it recites a narrower limitation (5 – 50 %) within a broader limitation (at least 5 – 50 %). It appears that the range is intended to reflect the total amount of MDI in the composition (2, 4'-MDI and 4, 4'-MDI) and thus would be more clearly stated by eliminating the limitation "at least". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 84 – 98 and 100 – 110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomson in US 2002/0018884 A1 in view of Pinchuk in US patent 5,229,431.

This new rejection, under USC 103(a), is necessitated by amendment to independent Claim 84 which adds the limitations of cancelled Claim 99 drawn to specific species of polyurethane polymers.

Thomson teaches a foam composite comprising reticulated hydrophobic polyurethane foam substrate that is coated with a coating comprising a hydrophilic polyurethane prepolymer (paragraph [0012]; Figure 1). Said hydrophilic coating can be a hydrophilic polyurethane foam coating (paragraph 0015). One embodiment comprises a coating comprising a mixture of a hydrophilic polyurethane and a hydrophilic hydrogel (paragraph [0130], instant Claim 88). Said hydrogel can be based on polysaccharides including alginate, carrageenan, agar, etc. (paragraph [0130]). Said polysaccharides are well-known in the art as "biodegradable". It is noted that claim 84 includes the limitation "the coating comprises a biodegradable polymer" and as such the examiner is taking into account the open language, i.e., the coating need not be fully biodegradable. Thomson also teaches embodiments that include an active ingredient in

the hydrophilic coating (paragraph [0014], instant Claims 84, 109). Said active ingredients include pharmaceutical, enzymes and human cells (paragraph [0147], instant Claims 84, 87 and 89). Thomson does not disclose an implant per se, as recited in the preamble to instant Claim 84, although it is clear that from the disclosure in which the polyurethane foam matrix serves as a femoral shunt, a drug delivery device, or a device to remove drugs from blood (Thomson, Figures 18, 20 and 22) that said polyurethane foams are clearly biocompatible materials and thus are implantable. It has been held that the intended use as cited in the preamble of a Claim is not relevant as the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use (implantation into a patient's body), then it meets the claim (MPEP 2111.02, II). Thomson contemplates coatings in the form of films and hydrogels (paragraphs [0092]-[0097] and [0130], instant Claims 101 and 102) as well as foams (Abstract, instant Claim 100). The polyurethane coating and hydrogels of Thomson read on non-biodegradable polymers as evidenced by paragraph [00179] of the instant specification (instant Claim 103).

Thomson is silent to including an active agent into the scaffold as well as the particular scaffold material containing polycarbonate polyurethane.

Pinchuk teaches a polycarbonate urethane foam suitable for medical prosthesis and implants which confer the properties of crack resistance and pliability (Abstract) as well as enhanced stability in vivo relative to polyurethanes comprising ether linkages

(column 6, lines 45 – 65, instant Claims 84, 98, 109 and 110). Pinchuk also teaches suitable medical prosthesis and implants include drug eluting matrices (column 3, line 4, instant Claim 85).

Regarding the limitations of instant Claims 90 and 91, Thomson teaches various shapes (paragraph [0071]). It is also noted that generally limitations drawn to shapes are not accorded patentable weight (see MPEP 2144.04 (I) and (IV)(A)-(B)). Regarding the limitations of instant Claims 86 and 92 – 97, said limitations are considered taught by the prior art, because the prior art of Thomson in combination with Pinchuk, teaches the claimed invention comprising the same materials.

Thomson teaches void volumes of up to 98% and pore size from 4 to 100 pores per linear inch (ppi) (paragraph [0070], instant Claims 107 and 108). Regarding the limitations of claims 104 –106, absent of a showing of evidence to the contrary, said pore sizes taught by Thomson read on the pore sizes claimed.

One of ordinary skill in the art would have been motivated, at the time the invention was made, to combine the particular material, polycarbonate urethane, taught by Pinchuk, into the foam composite of Thomson, in order to gain benefit of it's crack-resistance and improved pliability (Pinchuk, Abstract) as well as it's improved resistance to biodegradation (Pinchuk, column 6, lines 45 – 68 and column 7, lines 1 – 12) with a reasonable expectation of success. One skilled in the art would have additionally expected inclusion of an agent within the matrix to effectively elute into the body as taught by the polyurethane-polycarbonate implants of Pinchuk.

Claims 2, 3, 5, 7, 9 – 12, 61, 63 – 69, 72 – 76, 79 – 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomson (US 2002/0018884 A1) and Pinchuk in view of Van Antwerp (US 2003/0031699 A1).

Thomson in combination with Pinchuk teaches the elements discussed in the 103(a) rejection above. Thomson is silent to the limitation that the one or more therapeutic agents are contained in microspheres.

Van Antwerp teaches polymer coated implantable medical devices having a bioactive material posited in or on at least a portion of the coating layer, wherein the coating layer provides for controlled release of the bioactive material from the coating layer (abstract). Said coating can be hydrophilic or more specifically a hydrogel (paragraphs [0028], [0031] and [0035]). In a particular embodiment, Van Antwerp teaches that the coating comprises a bioactive that is encapsulated via e.g., a microsphere or microparticle (paragraphs [0062], [0080], [0082] and [0083]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Thomson and Van Antwerp because both teach hydrophilic coatings comprising an active agent for the purpose of controlled release of said active agent. One of ordinary skill in the art would have been motivated to incorporate the microspheres of Van Antwerp into the coating of Thomson because Van Antwerp teaches that the microspheres assist in further modulating or controlling the release of the active agent (see Van Antwerp at paragraphs [0080] and [0083]). A practitioner would have a reasonably expected a hydrophilic coating comprising microspheres containing a bioactive. Thus, in Thomson it would have been obvious to

one of ordinary skill in the art at the time the invention was made to incorporate microspheres as suggested by Van Antwerp.

Claim 111 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thomson in US 2002/0018884 A1 and Pinchuk in US patent 5,229,431 in view of Felt *et al.* in US patent 6,140,452.

As noted above Thomson in combination with Pinchuk teach the limitations on scaffold, coating and therapeutic agents of newly added Claim 111 previously addressed above in the rejection of instant Claim 84. Pinchuk teaches a combination of polymer precursors, including 4,4'-MDI, and several other structurally related aromatic diisocyanates (Pinchuk, column 6, lines 4 – 23) but the references do no teach the limitations drawn to the specific composition comprising the polymer precursors 2, 4'-MDI and 4, 4'-MDI at the recited weight percent limitations.

Felt teaches curable (polymerizable) polyurethane biomaterial compositions suited for prosthesis to repair tissue (Abstract). Felt further teaches a preferred embodiment at a total concentration between 30 and 50% by weight of an isocyanate component consisting of 2, 2'-MDI, 2, 4'-MDI and 4, 4'-MDI, and combinations thereof (column 8, lines 23 – 30). Felt teaches that the composition provides improved properties, including hardness, strength and/or cure characteristics without detriment to other properties including those that may occur following extended use in the body (column 8, lines 65 – 67 and column 9, lines 1 – 2). Felt teaches polyurethane compositions, when cured (polymerized), demonstrate an optimal combination of

properties, including stability, retention of physical shape, dissolution stability and biocompatibility (column 16, lines 43 – 51).

Felt does not teach a weight percent ratio of the specific MDI components, limiting the teachings to 'combinations thereof'. Nonetheless, absent evidence of unexpected results found with the recited broad ranges in instant Claim 111, one of ordinary skill in the art, in light of the guidance concerning the improved properties noted above of the preferred MDI components of Felt, would have been motivated to optimize, through routine experimentation, 2, 4'-MDI and 4, 4'-MDI at different relative weight percent combinations to arrive at the claimed invention.

Conclusion

Claims 2, 3, 5, 7, 9 – 12, 61, 63 – 68, 72 – 76, 79 – 98 and 100 – 111 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS HEYER whose telephone number is (571)270-7677. The examiner can normally be reached on Monday-Thursday 8AM-5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached at (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DH

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615